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EXAMINER

KRUSE, DAVID H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 06/11/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/727,511

Examiner

David H Kruse

Applicant(s)

ARNOLD ET AL.

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 22 February 2001 has been considered, a copy of which is attached hereto.

Specification

2. The disclosure is objected to because of the following informalities: Relevant text related to the claimed invention is missing on page 37, line 4, of the specification.

Appropriate correction is required.

Claim Objections

3. Claim 8 is objected to because of the following informalities: The phrase "A tissue culture" should read -- The tissue culture -- in referring to claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-32 are indefinite because the designation "LH246" does not denote an art recognized designation of corn plant and hence does not state the metes and bounds of the claimed invention. The ATCC Accession Number must be filled in where

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appropriate to clearly provide the identifying characteristics of Applicant's corn inbred line designated LH246. Compliance with this requirement may be held in abeyance since Applicant's specification provides evidence that the deposit has been or will be made. Applicant must provide the appropriate amendment to insert the deposit information at the time of allowance in both the specification and the claims.

Claim 6 is indefinite because the plant of claim 2 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

At claim 8, lines 1-2, the phrase "the cells or protoplasts of the tissue culture being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

At claim 9, line 2, the phrase "is capable of expressing" is indefinite because it does not denote a positive characteristic of the claimed corn plant and thus does not state the metes and bounds of the claimed invention. The term -- expresses -- is suggested.

At claim 10, line 4, the phrase "such a process" is indefinite and should read -- said process --.

Claim 17 is indefinite because the end product of the claimed method is a "seed" and the method is directed to producing "inbred LH246", not seed of the inbred corn line designated LH246. Appropriate correction is required.

Claim 18 is indefinite because it is unclear if the step is replacing step (c) at claim 17 or further limiting said step.

At claims 19-25, the term "LH246-derived" is indefinite because it is unclear from the instant specification what the metes and bounds of "derived" are. The instant limitation appears to be directed to LH246-prodgeny. Clarification is required.

At claims 20, 23, 25 and 29, the terms "high yield", "above average stalk strength", "above average test weight", "above average stay green", and "good stalk lodging resistance" are relative and do not state the metes and bounds of the claimed invention.

Claim 24 is indefinite because it is unclear where in the method of claim 19 plant tissue culture methods are utilized, what the metes and bounds of "utilizing" said methods are, and how "derived progeny" are produced "utilizing" plant tissue culture methods. The claim is, in general, narrative and does not denote a positive method step.

Claim 25 is indefinite because the method of claim 24 appears to produce a further "derived" LH246-derived corn plant, hence claim 25 does not properly further limit claim 24, but appears to be directed to the product of the method of claim 19.

Claim 27 is indefinite because the claimed method only recites the method step of "crossing" at line 2, but does not recite any additional step(s) leading to the production of a corn plant that contains in its genetic material one or more transgenes.

Claim 28 is indefinite because the method of claim 27 indefinite for the reasons given above, hence there is no clear indication that "corn plants" are produced by the

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method of claim 27. In addition, the limitation "Corn plants" lacks a proper antecedent basis in claim 27 because the method is directed to making "a corn plant". Appropriate correction is required.

Claim 30 is indefinite because the claimed method of developing a corn plant using plant breeding techniques does not recite any positive method steps by which one could practice the claimed method.

Claim 31 is indefinite because it fails to properly limit the method of claim 30. Claim 30 is directed to a method for developing a corn plant and not to a corn breeding program. Hence, it is unclear what the metes and bounds of claim 31 are.

Claim 32 is indefinite because the method of claim 30 does not recite a method step by which a corn plant is produced, as discussed above.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12-16, 20-23, 25-29, 31 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants and transgenic corn plants

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having undisclosed identifying characteristics whereby only the characteristics of the deposited corn line LH246 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 26 and 28, the effect of transgenes on the physiological and morphological characteristic of a transgenic LH246 corn plant or progeny thereof, is not sufficiently described where by one of skill in the art could recognize the claimed corn plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. While claims 20, 23, 25 and 29 set forth at least two LH246 traits, because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish LH246 progeny plants. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited corn line LH246. Accordingly, there is a lack of adequate description of the claimed progeny plants, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of

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the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

8. Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant or will deposit the plant but there is no indication in the specification as to public availability.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without

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restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

9. Claims 26-28 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because Applicant has failed to adequately describe the corn plant having been transformed so that its genetic material contains one or more

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transgenes as claimed in claim 26 as discussed supra, the method for producing a corn plant of claim 27 and the corn plant produced by the method of claim 27 at claim 28 are not enabled. One skilled in the art would not know how to use a plant that has not been adequately described.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12-16, 20, 22, 23, 25, 29 and 32 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Foley (U.S. Patent 5,059,745).

Foley discloses an inbred corn line designated LH195 (see claim 1), which Applicant admits is similar to the inbred corn line of the instant invention (see page 13, paragraph 3 of the instant application). Said LH195 inbred corn line inherently discloses

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such relative traits as “good yield”, “above average stalk strength” and “good stalk lodging resistance” (see for example, columns 5 and 6). Applicant should also note that because the limitations set forth in the claims lack a comparative basis as set forth in the 112 second paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Foley in the instant reference. While the inbred corn line of Foley is designated LH195 and the parent corn variety of the instant claims is designated LH246, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art.

Foley does not specifically disclose a method of producing corn plants using LH246 as a parent in an unspecified number of crosses with unspecified second parents.

The hybrid corn seed and hybrid corn plant of claims 12 and 13 would have been *prima facie* obvious to one of skill in the art at the time of applicant's invention because, depending upon what second inbred corn plant one of skill in the art had selected, the resulting corn seed and progeny could be genetically, morphologically and physiologically indistinguishable from that of the instant claims. Similarly, the corn seed of claim 14 and the F1 hybrid seed and plant of claims 15 and 16 would have been obvious in view of the teachings of the Foley reference. The LH246-derived corn plant of claims 20, 22, 23, 25, 29 and 32 would also have been obvious in view of the Foley reference because again, depending upon what second corn plant one of skill selects in producing said “derived” corn plant, the resulting progeny could be genetically, physiologically and morphologically indistinguishable from that of the claimed LH246-

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derived corn plant, given the loss of LH246-derived genetic material with each outcross to a non-LH246 parent. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

13. Claims 1-11, 17-19, 21,24, 26-28, 30 and 31 appear to be free of the prior art because it neither suggests nor teaches the LH246 inbred corn line of the instant claims or methods of use.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
6 June 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

